

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**OSTEOTECH, INC.,**

**Plaintiff,**

**v.**

**REGENERATION TECHNOLOGIES,  
INC.,**

**Defendant.**

**Civil Action No. 06-4249 (FLW)**

**ORDER**

This matter having been opened to the Court upon Motion by Plaintiff Osteotech, Inc. (“Osteotech”) seeking an Order permitting it to amend its Complaint to add a claim for infringement of U.S. Patent No. 5,513,662 (the “‘662 patent”) [Docket Entry No. 52]; and Osteotech arguing that pursuant to FED.R.CIV.P. 15, which states that leave to amend the pleadings should be “freely” granted, Osteotech should be permitted to add a claim for infringement of the ‘662 patent, which is related to U.S. Patent No. 5,33,626 (the “‘626 patent”), the patent at issue in Osteotech’s original Complaint; and Osteotech further arguing that permitting it to pursue both patents in one litigation will gain efficiencies and save resources for both the parties and the Court; and Osteotech further arguing that its proposed amendment will not prejudice Defendant Regeneration Technologies, Inc. (“RTI”) because (1) discovery in the matter has not ended, (2) only one deposition has occurred so far in this matter, and, approximately three months before that deposition occurred, Osteotech sought RTI’s consent to its proposed amendment, (3) “pre-litigation discussions between the parties included both the ‘626 and ‘662 Patents[,]” (Osteotech Br. at 3), and (4) RTI’s third party subpoenas sought information relating to both patents; and Osteotech further arguing that the lack of prejudice to RTI is decisive of the issue of whether Osteotech should be permitted to amend its Complaint;

and Osteotech further arguing that, while the lack of prejudice to RTI is decisive, Osteotech's amendment would also not unduly delay these proceedings; and Osteotech further arguing that notably no deadline for the filing of amended pleadings has even been set yet by the Court, let alone expired; and Osteotech further arguing that on November 9, 2007, less than a year after serving its original Complaint on RTI, and less than four months after the Court entered a Protective Order permitting the first production of internal documents, which (according to Osteotech) confirmed that RTI's bone cleaning process infringes the '662 patent, Osteotech sought RTI's consent to file its proposed amendment; and Osteotech further arguing that rather than consenting to the filing of its clearly appropriate proposed Amended Complaint, RTI refused to explicitly consent or reject Osteotech's proposed amendment, and, instead, used the threat of its refusal as leverage in an effort to obtain more discovery on the '626 patent than it had offered itself; and Osteotech further arguing that after having attempted to gain RTI's consent for three months, on February 21, 2008, it filed the instant Motion to Amend; and Osteotech further arguing that in considering whether there has been undue delay, the Court "focuses on delay after filing of initial pleadings" (Osteotech Reply at 10); and Osteotech further arguing that RTI's arguments that Osteotech should have brought suit on the '662 patent during the past nine years are not only "unsupported by evidence or common sense[.]" but more importantly are irrelevant to the issue of undue delay under FED.R.CIV.P. 15 (Osteotech Reply at 10); and Osteotech further arguing that its proposed amendment is not futile; and Osteotech further arguing that RTI has failed to cite law supporting its claims that Osteotech's proposed Amended Complaint would not survive a motion to dismiss based on laches or statute of limitations grounds; and Osteotech further arguing that RTI's argument that Osteotech should be estopped from bringing the claims

asserted in its proposed Amended Complaint similarly fails both because RTI provides no support for that argument and because, even if supported, such an argument is inappropriate since equitable estoppel defenses are factual in nature and therefore could not render Osteotech's proposed amendment futile; and Osteotech further arguing that contrary to RTI's assertion, there is no basis for finding its proposed amendment to be futile on the grounds that it expands the case to include some unknown and undefined methods for cleaning and sterilizing bone because "the RTI process it accuses of infringing the '662 Patent is exactly the same process it accuses of infringing the '626 Patent" (Osteotech Reply at 14); and Osteotech further arguing that it did not bring the instant Motion to Amend in bad faith, nor was it dilatory in seeking the proposed amendment; and RTI having opposed Osteotech's Motion; and RTI arguing that "Osteotech's proposed amendment is not in the interests of justice" and therefore should not be granted pursuant to FED.R.CIV.P 15 (RTI Opp. at 1); and RTI further arguing that Osteotech's undue and unexplained delay is fatal to its Motion to Amend; and RTI further arguing that "courts routinely deny motions to amend where the plaintiff had the necessary information to assert the new claim when it filed its original complaint" (*Id.* at 3); and RTI further arguing that Osteotech waited nearly nine years after RTI began openly using BioCleanse before it decided to assert the '662 patent against RTI; and RTI further arguing that Osteotech has known about BioCleanse, including its alleged use of "negative pressure", for years; and RTI further arguing that according to Osteotech's own admission, Osteotech was aware of alleged issues surrounding the '662 patent as early as March 2004; and RTI further arguing that at a minimum, Osteotech knew about the alleged issues surrounding the '662 patent more than two and a half years before Osteotech filed its original Complaint, and, therefore, Osteotech has unreasonably delayed in seeking to

amend that Complaint now; and Osteotech further arguing that RTI should not be allowed to benefit from its tactical decision to delay in bringing its claims regarding the '662 patent when it had all the information necessary to file suit on the 662 patent years ago; and RTI further arguing that Osteotech fails to meet its burden of explaining the years-long delay, but instead feigns diligence by claiming that "RTI produced documents 'supporting' Osteotech's allegations on November 6, 2007" (*Id.* at 5); and RTI further arguing that Osteotech does not, however, claim that the documents produced by RTI "constituted Osteotech's first knowledge of the relevant facts[,] nor could it because "Osteotech knew of these facts long ago" (*Id.*); and RTI further arguing that Osteotech has brought its Motion to Amend in bad faith; and RTI further arguing that courts have held that undue delay that is not satisfactorily explained amounts to bad faith; and RTI further arguing that here, Osteotech's undue and unexplained delay, combined with its tactical decision to now assert the '662 patent constitutes bad faith; and RTI further arguing that Osteotech created an objective basis for believing that it was not going to pursue its claims regarding the '662 patent when, after previously having contacted RTI regarding both the '626 and '662 patents, it filed its original Complaint that only raised the '626 patent; and RTI further arguing that it raised the issue of the '662 patent in the March 2007 Joint Discovery Plan, and that Osteotech did nothing to change RTI's objective belief that Osteotech had dropped its claims regarding same; and Osteotech further arguing that it was not until after RTI advised that it would be filing a motion for summary judgment regarding the '626 patent that Osteotech decided to pursue the '662 patent; and RTI further arguing that the timing of Osteotech's decision to pursue the '662 patent reveals bad faith and is also indicative of Osteotech's dilatory motive; and RTI further arguing that it will be prejudiced if Osteotech is allowed to file its untimely proposed

Amended Complaint; and RTI further arguing that the ‘662 patent is quite different from the ‘626 patent and allowing Osteotech to amend at this time would require RTI to redo a substantial amount of discovery that has already been conducted; and RTI further arguing that because the ‘662 patent has new filing, priority and issue dates, as well as new claims directed to new materials, RTI would have to conduct all new discovery regarding invalidating prior art; and RTI further arguing that it would also have to change its focus from the methods disclosed in the ‘626 patent (i.e. “the use of high velocity jet streams and vigorous agitation to clean bone” (RTI Opp. at 8)) and reverse course to focus on “negative pressure”; and RTI further arguing that contrary to Osteotech’s arguments it would be prejudiced because (1) it has already subpoenaed and deposed Brenda Morse, the inventor of both the ‘626 patent and the ‘662 patent, and because RTI filed the instant Motion to Amend less than two days before Ms. Morse’s deposition, RTI was not prepared to, nor did it depose Ms. Morse on the ‘662 patent, (2) RTI focused its discovery on the cleaning techniques disclosed in the ‘626 patent, not the ‘662 patent, and while RTI sought some discovery relevant to the ‘662 patent, it only did so if the information bore on issues relating to the ‘626 patent, which would necessitate the taking of substantial additional discovery if Osteotech’s amendment is permitted, (3) as with the discovery directed toward Osteotech, RTI focused its third-party discovery on cleaning techniques disclosed in the ‘626 patent, not the ‘662 patent and forcing RTI to return to these reluctant third parties for additional discovery will be prejudicial to RTI, (4) contrary to Osteotech’s assertions, discovery in this matter is nearly complete and allowing Osteotech’s proposed amendment would require substantial additional discovery efforts, and (5) RTI has already filed a motion for summary judgment (which is fully briefed) to limit Osteotech’s alleged damages on the ‘626 patent, and if Osteotech is permitted to

file an Amended Complaint asserting claims on the ‘662 patent, RTI will be forced to brief another motion on the same damages issue; and RTI further arguing that Osteotech’s proposed amendment should also be denied because it is futile; and RTI further arguing that Osteotech’s proposed amendment is futile because Osteotech “is estopped from bringing this years-old claim now” (*Id.* at 10); and RTI further arguing that Osteotech’s proposed amendment is also futile because it seeks to expand the scope of this matter to include unidentified “methods for cleaning and sterilizing bone” without identifying what “mystery method[s]” it is referring to, thereby rendering it impossible for this Court to analyze the futility of the proposed amendment (*Id.* (quoting Osteotech Ex. A. ¶18)); and the Court having fully reviewed and considered Osteotech’s moving papers, as well as RTI’s opposition, and Osteotech’s reply thereto; and the Court finding that leave to amend the pleadings under FED.R.CIV.P. 15(a) is generally given freely (*Foman v. Davis*, 371 U.S. 178, 182 (1962); *see Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000)); and the Court further finding, that nevertheless, it may deny a motion to amend where there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of the amendment”(*Id.*); and the Court further finding that where there is an absence of undue delay, bad faith, prejudice or futility, a motion for leave to amend a pleading should be liberally granted (*Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004)); and the Court further finding that “prejudice to the non-moving party is the touchstone for the denial of the amendment” (*Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989)(*quoting Cornell & Co., Inc. v. Occupational Health and Safety Review Comm’n*, 573 F.2d 820, 823 (3d Cir. 1978))); and the Court further finding that to establish prejudice, the non-moving party must make a showing

that allowing the amended pleading would (1) require the non-moving party to expend significant additional resources to conduct discovery and prepare for trial, (2) significantly delay the resolution of the dispute, or (3) prevent a party from bringing a timely action in another jurisdiction (*Long*, 393 F.3d at 400); and the Court further finding that delay alone does not justify denying a motion to amend (*see Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001)); and the Court further finding that it is where delay becomes “‘undue,’ placing an unwarranted burden on the court, or . . . ‘prejudicial,’ placing an unfair burden on the opposing party” that denial of a motion to amend is appropriate (*Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984); and the Court further finding that unless the delay at issue will prejudice the non-moving party, a movant does not need to establish a compelling reason for its delay (*see Heyl & Patterson Int'l, Inc. v. F. D. Rich Housing of Virgin Islands, Inc.*, 663 F.2d 419, 426 (3d Cir. 1981)); and the Court further finding that “the mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay” (*Cureton*, 252 F.3d at 273); and the Court further finding that delay may become undue when there has been previous opportunity to amend the complaint (*see Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (finding that a three-year lapse between the filing of the complaint and the proposed amendment was “unreasonable” delay when plaintiff had previous opportunities to amend)); and the Court further finding that, as such, in determining whether the delay is in fact undue, the Court must focus on the moving party’s reasons for not amending the pleading sooner (*USX Corp. v. Barnhart*, 395 F.3d 161, 168 (3d Cir. 2004)); and the Court further finding that like undue delay, in examining bad faith, the Court also looks at the moving party’s reasons for not amending earlier (*see Lyon v. Goldstein*, Civil Action No. 04-3458 (MLC), 2006 WL 2352595, at \*4 (D.N.J. Aug. 15, 2006));

and the Court further finding that a proposed amendment is futile when it would not survive a motion to dismiss (*Alvin*, 227 F.3d at 121 (3d Cir. 2000)); and the Court further finding that in evaluating a motion to dismiss, the Court “must accept as true all of the factual allegations contained in the complaint” as well as the reasonable inferences that can be drawn from them (*Erickson v. Pardus*, 127 S.Ct. 2197, 2200 (2007)); and the Court further finding that “[w]hile a Complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do” (*County of Hudson v. Janiszewski*, 520 F.Supp. 2d 631, 639 (D.N.J. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007) (internal quotation marks and citations omitted)); and the Court further finding that Osteotech’s Motion to Amend is timely; indeed, the Court notes that as yet, no deadline has been set for the filing of motions to amend the pleadings; and the Court further finding that fact discovery in this matter remains open, and, consequently, if this Court permits Osteotech’s proposed amendment, RTI will have an opportunity to obtain the discovery needed to defend against Osteotech’s new claims; and the Court further finding that while it is clear that the addition of Osteotech’s proposed amendment will certainly require further discovery to be taken, it appears equally clear that RTI has already obtained much, though certainly not all, discovery relevant to Osteotech’s proposed claims regarding the ‘662 patent; and the Court further finding that to date, only one deposition has occurred<sup>1</sup>, and, as a result, RTI would not have to expend significant extra resources in re-

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<sup>1</sup>The Court also notes that while this deposition occurred only days after Osteotech filed its Motion to Amend, it occurred months after Osteotech first sought RTI’s consent to its proposed amendment. The Court is therefore not moved by RTI’s argument that Osteotech’s undue delay



deposing witnesses with knowledge of both the '626 and '662 patent; and the Court further finding that while RTI has already filed a Motion for Summary Judgement, seeking to limit Osteotech's alleged damages with respect to its claims regarding the '626 patent, RTI's argument that it may have to file another similar motion with respect to the '662 patent does not carry much weight in the Court's analysis because (1) the District Court's determination with respect to the first motion will be precedential and may obviate the need for a second motion and (2) even if a second motion is required, it will be guided by the District Court's initial decision, and therefore, significant additional resources will not need be expended pursuing same; and the Court further finding that in analyzing Osteotech's delay in seeking its proposed amendment, the Court focuses on the time that has elapsed since the filing of the initial complaint<sup>2</sup>; and the Court further finding that here, Osteotech filed its initial Complaint on September 11, 2006; and the Court further finding that, with Osteotech's consent, RTI's time within which to answer, move or otherwise reply to that Complaint was extended until January 5, 2007, the date on which RTI filed its Answer; and the Court further finding that while originally set for January 9, 2007, the Initial Conference in this matter did not take place until April 5, 2007; and the Court further

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caused it to be unprepared to depose Brenda Morse, the inventor of both the '626 and '662 patents, on the '662 patent.

<sup>2</sup>The Court has considered RTI's argument that Osteotech's Motion to Amend should be denied because Osteotech unduly and inexplicably delayed in bringing it claims on the '662 patent, which Osteotech could have brought years ago. However, as noted above, in examining alleged undue delay in the context of a motion to amend, the Court focuses only on the period of time that has elapsed from the filing of the initial complaint. RTI's arguments regarding Osteotech's failure to bring suit on the '662 patent prior to September 11, 2006, the date on which Osteotech filed its initial Complaint, are therefore misplaced. The Court finds that such arguments bear on fact sensitive defenses such as laches and/or equitable estoppel and would more appropriately be the subject of a motion for summary judgment.

finding that it was not until July 18, 2007 that a protective order was entered in this matter, which allowed the parties to exchange confidential, internal documents; and the Court further finding that Osteotech argues that it was not until after it obtained and reviewed certain of RTI's confidential, internal documents that Osteotech was able to confirm that RTI's bone cleaning process infringed the '662 patent; and the Court further finding that on November 9, 2007, Osteotech sought RTI's consent to the proposed amendment at issue in the instant Motion; and the Court further finding that Osteotech informed RTI of its intent to amend its Complaint fourteen months after it filed its original Complaint, ten months after RTI filed its Answer, seven months after the Court held the Initial Conference in this matter, and a mere four months after the Protective Order in this matter was entered; and the Court further finding that unlike the cases relied upon by RTI, in which the plaintiffs waited three or more years to seek to amend their complaints, here, Osteotech sought RTI's consent to its proposed amendment only fourteen months after it filed its initial Complaint; and the Court further finding that even assuming that little weight should be given to Osteotech's argument that its decision to amend was prompted by information obtained in discovery that was not obtained until after the Protective Order was entered, the Court finds that under the circumstances of this case, Osteotech's Motion to Amend is not the product of undue delay, nor did it result from bad faith or a dilatory motive; and the Court further finding that because Osteotech's proposed amendment will not unreasonably delay these proceedings, because RTI will be able to obtain any additional discovery needed to defend against Osteotech's proposed Amended Complaint and because RTI will not have to expend significant additional resources to pursue the discovery needed to mount this defense, Osteotech's proposed amendment will not unduly prejudice RTI; and the Court further finding

that RTI has failed to establish that Osteotech's proposed amendment, which Osteotech has stated involves "exactly the same process it accuses of infringing the '626 Patent[.]" is clearly futile (Osteotech Reply at 14); and the Court having considered this matter pursuant to FED.R.CIV.P. 78, and for good cause shown,

IT IS on THIS 9th day of May, 2008,

ORDERED that Osteotech's Motion to Amend is GRANTED; and it is further

ORDERED that Osteotech shall file its Amended Complaint no later than **May 16, 2008**; and it is further

ORDERED that the Clerk of the Court terminate this Motion [Docket Entry No. 52] accordingly.

s/ Tonianne J. Bongiovanni  
**TONIANNE J. BONGIOVANNI**  
**UNITED STATES MAGISTRATE JUDGE**